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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
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STERILE COMPOUINDING SELF-ASSESSMENT

The contents of this self-assessment may be used as a guide by pharmacies applying for a sterile compounding license to determine compliance with all areas of the regulations governing sterile compounding.

Complete texts can be found in Title 16 of California Code of Regulations (CCR) sections 1751 (revised) and following, and Business and Professions Code sections 4127, 4127.7

Designation = C means compliant, NC means non-compliant

CCR 1751: COMPOUNDING AREA

C	NC	
☐	☐	Clean room with walls, ceilings and floors are made of non-porous, cleanable surfaces.
☐	☐	Well ventilated.
☐	☐	Laminar air flow hoods and clean room certified annually.
☐	☐	Supplies stored in a manner which maintains integrity of an aseptic environment.
☐	☐	A sink with hot and cold running water.
☐	☐	A refrigerator of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

CCR 1751.01: FACILITY AND EQUIPMENT STANDARDS FOR STERILE INJECTABLE COMPOUNDING FROM NON-STERILE INGREDIANTS

On or after July 1, 2005, the following shall apply to any pharmacy compounding sterile injectable products from one or more non-sterile ingredients.

C	NC	
☐	☐	A ISO class 5 (class 100) laminar air flow hood within a ISO class 7 (class 10,000) clean room (with positive air pressure differential relative to adjacent areas)
		OR
☐	☐	A ISO class 5 (class 100) clean room with positive air pressure differential relative to adjacent areas.
		OR
☐	☐	A barrier isolator that provides a ISO class 5 (class 100) environment for compounding.
☐	☐	No sterile injectable product prepared if it is known or reasonably should have known that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.
☐	☐	Access to designated area or clean room limited to those individuals who are properly attired.
☐	☐	All equipment used in the designated area or clean room must be made of a material that can be easily cleaned and disinfected.
☐	☐	Exterior workbench surfaces and other hard surfaces in the designated area such as walls, floors, ceilings, shelves, tables and stools must be disinfected weekly and after any unanticipated event that could increase risk of contamination.

CCR 1751.02: POLICIES AND PROCEDURES

Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include but not limited to:

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☐	☐	Compounding, filling, and labeling of sterile injectable compounds
☐	☐	Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
☐	☐	Equipment and supplies
☐	☐	Training of staff in the preparation of sterile injectable products
☐	☐	Quality Assurance Program
☐	☐	Record keeping requirements
☐	☐	The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.
☐	☐	Written policies and procedures immediately available to all personnel involved the compounding activities and Board of Pharmacy Inspectors.
☐	☐	All personnel involved must read the policies and procedures before compounding sterile injectable products and any additions, deletions, and revisions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.

Policies and procedures must address at least the following:

C	NC	
☐	☐	Staff competency evaluations
☐	☐	Storage and handling of products and supplies
☐	☐	Storage and delivery of final product
☐	☐	Process validation
☐	☐	Personnel access and movement of materials into and near the compounding area
☐	☐	Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g. laminar air flow workstations, biological safety cabinet, class 100 clean room, and barrier isolation workstations).
☐	☐	Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants (pharmacies subject to an institutional infection control policy may follow that policy.
☐	☐	Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.
☐	☐	For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
☐	☐	Sterilization procedures exist (including documentation of sterilization results).
☐	☐	End-product evaluation and testing occurs

CCR 1751.2: LABELING REQUIREMENTS

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☐	☐	Labels to include telephone number of pharmacy (exemption: sterile injectable products dispensed for inpatients of a hospital).
☐	☐	Name and concentration of ingredients contained in the product
☐	☐	Instructions for storage and handling
☐	☐	All cytotoxic agents shall bear a special label which states *"Chemotherapy-Dispose of Properly"*

CCR 1751.3: RECORD KEEPING REQUIREMENTS

C	NC	
☐	☐	There is an immediately retrievable patient medication profile for each patient.
☐	☐	Pharmacies compounding sterile injectable products for future use shall also have records indicating the name, lot number, amount, and date on which the products were provided to the prescriber.
☐	☐	Maintenance of records for three years to include:
☐	☐	Training and competency evaluation of employees in sterile product procedures.
☐	☐	Refrigerator and freezer temperatures are monitored and documented.
☐	☐	Certification of the sterile compounding environment occurs on a regularly scheduled basis according to written policies and procedures.
☐	☐	Other facility qualify control logs specific to the pharmacy's policies and procedures are maintained (e.g. cleaning logs for facilities and equipment).
☐	☐	Inspection records for expired or recalled pharmaceutical products or raw ingredients exists.
☐	☐	Preparation records including the master work sheet, the preparation work sheet and records of end-product evaluation.

CCR 1751.4: ATTIRE

C	NC	
☐	☐	When preparing cytotoxic agents, gowns and gloves are worn.
☐	☐	Clean room garb consists of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
☐	☐	Clean room garb must be donned and removed outside the designated area.
☐	☐	Hand, finger, and wrist jewelry must be removed. If jewelry cannot be removed, the jewelry must be thoroughly cleaned and covered with a sterile glove.
☐	☐	Head and facial hair must be kept out of the critical area or be covered.
☐	☐	Protective gloves made of low-shedding materials are required.

Note: Requirements may not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredient.

CCR 1751.5: TRAINING OF STAFF, PATIENT, AND CAREGIVER

C	NC	
☐	☐	Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
☐	☐	The pharmacist in charge shall ensure all personnel engaging in compounding sterile injectable drug products shall have training and demonstrate on-going competence in the safe handling and compounding of sterile injectable drug products including cytotoxic agents.
☐	☐	Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.
☐	☐	Pharmacies must have an established and follow a written program of training performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly.
☐	☐	The program of training and evaluation shall address the following: aseptic technique, pharmaceutical calculations/terminology, sterile products compounding documentation, quality assurance procedures, aseptic preparation procedures, proper gowning and gloving techniques, general conduct in the controlled area, cleaning/sanitizing and maintaining equipment used in the controlled area, sterilization techniques, container, equipment and closure system selection.

☐ ☐ Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices.

☐ ☐ Evaluations must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.

☐ ☐ Each person's proficiency and continuing training needs must be reassessed every 12 months.

☐ ☐ Results of staff assessments must be documented and retained in the pharmacy for three years.

CCR 1751.6: DISPOSAL OF WASTE MATERIAL

C NC

☐ ☐ Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residue.

☐ ☐ Procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.

CCR 1751.7: QUALITY ASSURANCE AND PROCESS VALIDATION

C NC

☐ ☐ Each pharmacy shall have a documented, ongoing quality assurance program that monitors personnel, performance, equipment and facilities.

☐ ☐ The end product shall be examined on a periodic sampling basis as determine by the pharmacist in charge to assure that it meets required specifications.

Quality Assurance program shall include:

☐ ☐ Cleaning and sanitization of the parenteral medication preparation area.

☐ ☐ Written documentation that the end product has been tested on a periodic sampling basis for microbial contamination and steps taken in the event that testing for contamination proves positive.

☐ ☐ The storage of compounded parenteral products in the pharmacy and periodic documentation of refrigerator/freezer temperature.

☐ ☐ Steps taken in the event of a drug recall.

☐ ☐ Written justification of the chosen expiration dates for compounded sterile injectable drug products.

Process Validation:

☐ ☐ Each individual involved in the preparation of sterile injectable products from one or more non-sterile ingredients must successfully complete a validation process before being allowed to prepare sterile products.

☐ ☐ The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used to test the sterility of the final product.

☐ ☐ The same personnel, procedures, equipment, and materials are involved.

☐ ☐ Completed medium samples must be incubated.

☐ ☐ If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated.

☐ ☐ Personnel competency must be revalidated at least every 12 months, whenever the quality assurance program yields an unacceptable result, or whenever improper aseptic techniques are observed.

☐ ☐ The validation and revalidation process must be documented.

CCR 1751.9 : REFERENCE MATERIALS

C	NC	
☐	☐	There must be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.